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REMARKS

The amendment does not involve new matter. Claims 32 and 33 are supported by page 5, lines 4-11; page 11, lines 19-21 and page 12, lines 1-3 of the application.

Claims 6, 11, 24-27, 30 and 31 were rejected in the outstanding Office Action under 35 U.S.C. §103(a) as unpatentable over U. S. Patent No. 5,480,668 (Nofre '668) in view of U.S. Patent No. 4,997,659 (Yatka). This rejection is respectfully traversed. Claims 6, 24-25 and 30 require using a N-substituted derivative of aspartame as part of a rolling compound on a chewing gum product. Claims 11, 26-27 and 31 require using an N-substituted derivative of aspartame as part of a coating formed by panning a chewing gum pellet . While Nofre '668 discloses the N-substituted derivatives of aspartame used in the present invention, Nofre makes no suggestion for using the disclosed sweeteners in a rolling compound for chewing gum or in a panned chewing gum coating.

Yatka, on the other hand, discloses different ways of using a completely different sweetener, alitame, in chewing gum. While Yatka discloses using alitame as a part of a rolling compound and in a pellet coating, there is no suggestion in Yatka to use other sweeteners in this fashion. There is no reason from the references themselves to combine the references and treat N-substituted derivatives of aspartame the way alitame was treated. This rejection is thus based on hindsight.

Just because one high-potency sweetener was used in a particular fashion in producing chewing gum does not mean that it would have been obvious to use other high-potency sweeteners in the same fashion. Moreover, alitame was suggested for use in these ways in Yatka because of a desire to delay its release or separate it from other ingredients which may cause the alitame to degrade. The need for delayed release or prevention of degradation has not been shown in the prior art as being applicable to N-substituted derivatives of aspartame. Rather, Nofre '668 shows the stability of the N-substituted derivatives of aspartame disclosed therein when used in chewing gum (see col. 3, lines 51-60); and there is no suggestion that the materials release too quickly from chewing gum.

The Office Action takes the position that alitame is a well known sweetener, and the ways alitame are used in Yatka would make it obvious to apply the teachings of Yatka to "other conventional chewing gum sweeteners." Later, the Office Action implies that alitame and neotame are "different but similar" sweeteners. At the time of the present invention, neotame could not be considered to be a conventional chewing gum sweetener. While its use in chewing gum is suggested by Nofre '508, that does not make it a conventional sweetener. Neotame was not even approved for use as a sweetener in food in the U.S until July, 2002 (see page NCB of brochure titled "New Approaches to the Product Developer's Dilemma" from the NutraSweet Company, four pages, attached hereto as Appendix A) (hereinafter referred to as Neotame Brochure"), which was well after the 1998 effective filing date for the present application. Also, neotame has quite distinct properties compared to alitame. While neotame has a water solubility of at 25°C of 1.3% (Neotame Brochure, page NCD), alitame has a water solubility 10 times greater, 13.1% (see fourth page of collection of pages from Pfizer brochure on Aclame (its trade name for alitame), attached hereto as Appendix B). This difference in solubility is one of the reasons alitame release from chewing gum much more quickly than neotame. Further, since neotame has a dimethlybutyl addition to its chemical structure, it is lipophilic, and thus it becomes more easily bound to the gum base, again making it release more slowly from chewing gum than alitame.

At the bottom of page 3, the Office Action also takes the position that Nofre '668 does not support Applicants' position that N-substituted derivatives of aspartame are more stable in chewing gum than aspartame. However, Nofre '668 col. 3, lines 51-60 teaches that N-substituted derivatives of aspartame are more stable than aspartame under the common conditions of use for food preparations, and notes that the N-substituted derivatives will be better than aspartame for stability in foods that have a pH around 7, such as chewing gum.

The first full paragraph on page 3 of the Office Action includes some statements that are incorrect. Applicants did not conclude that applying alitame to chewing gum in a panning procedure will delay its release. In fact, they believe it will increase its release. Rather, Applicants remarks point out that Yatka teaches applying alitame in a gum coating to separate it from other gum ingredients, to thereby improve its stability.

Second, the third sentence refers to using a panning procedure to apply a sweetener to chewing gum as part of a rolling compound. However, panning procedures are used to produce shell coatings on gum pellets, not apply rolling compounds. Rolling compounds are used as dusting agents during processing of stick and tab gum products.

Claims 6, 11, 24-27, 30 and 31 were rejected in the outstanding Office Action under 35 U.S.C. §103(a) as unpatentable over U. S. Patent No. 5,510,508 (referred to on the face of the patent as Claude et al., but referred to in the Office Action as Nofre et al. 5,510,508, and referred to herein as Nofre '508) or Nofre '668 in view of U.S. Patent No. 4,374,858 (Glass) and Yatka. This rejection is respectfully traversed. Nofre '508 discloses methods of preparing a particular N-substituted derivative of aspartame, but the same material is disclosed in Nofre '668. Nofre '508 also suggests that the compound can be used in chewing gum, but so does Nofre '668. There is no suggestion in Nofre '508 of using the particular N-substituted derivative of aspartame in a rolling compound or panned coating on a chewing gum pellet. Thus Nofre '508 is considered to be cumulative to Nofre '668.

Glass discloses an aspartame sweetened chewing gum, including the use of aspartame in a rolling compound. Col. 4, lines 16-38 outline a test that was conducted to show that aspartame used in this fashion was more stable than aspartame mixed into a chewing gum composition. However, there is no suggestion of using other high-intensity sweeteners in the same fashion, and no suggestion of using N-substituted derivatives of aspartame.

Just as with the rejection based on Nofre '668 in view of Yatka, there is no explanation in the Office Action of any motivation for combining the references. There in no suggestion in Nofre '668, Nofre '508, Glass or Yatka of using a sweetener used in the way disclosed in one reference the same way that sweeteners used in another reference are used. It is only by hindsight of the present invention that one would consider combining these references. Further, since Nofre '668 teaches that N-substituted derivatives of aspartame are stable in chewing gum compared to aspartame, there would be a no reason from Nofre '668 to use N-substituted derivatives

in a manner that aspartame was used in Glass to increase its stability. Thus, claims 24 and 26, and the claims dependent thereon, are patentable over the cited references.

The second paragraph on page 4 of the Office Action states that "aspartame is quite similar in its properties to applicant's claimed N-substituted aspartame". This position is traversed. First, it is clarified that claims 24 and 26 call for N-substituted derivatives of aspartame, not N-substituted aspartame. Next, it is noted that neotame, the specific N-substituted derivative listed in claims 30 and 31, is significantly different than aspartame. Neotame is 30-60 times sweeter than aspartame, and is thus used in food at considerably lower concentrations. (*See Neotame: The Next-Generation Sweetener, Food Technology*, vol. 56, No. 7, (July 2002) p.37, attached hereto as Appendix C) (hereinafter referred to as "*Food Technology*"). While its solubility in water is similar to that of aspartame, its lipophilic properties make it more readily soluble in some solvents typically used in food systems. *Food Technology,* p.37. Thus, neotame, and the other N-substituted derivatives of aspartame referred to in Applicants' claims, are not "quite similar" to aspartame. While it is true that they are chemically similar, their properties are quite different, especially in regard to those properties that are important to their use in chewing gum, such as how they interact with gum base and the level at which they are used.

Claims 32 and 33 specifically cover utilizing the N-substituted derivative of aspartame in a manner that results in faster release than if the N-substituted derivative of aspartame were added to the gum in an untreated fashion. Claims 32 and 33 are thus further patentable over the cited references.

Since each of the reasons for the rejections have been overcome, it is believed that the case is in condition for allowance. However, since the last Office Action was a final rejection, Applicants are filing a notice of appeal herewith.

Respectfully submitted,

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Dated: February 3, 2006

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APPENDIX B

Pfizer FOOD SCIENCE

PFIZER FOOD SCIENCE, DIVISION OF PFIZER PTY LIMITED, ACN 008 422 348, 38 WHARF ROAD, WEST RYDE, NSW 2114.
*TRADEMARK PFIZER INC. 6/95 S&H PFSAL0010

ADDING SWEETNESS, NOT CALORIES.

For sweetening reduced and low-calorie foods and beverages, Aclame is the wise choice.

With a caloric content of just 1.4kcal per gram and high potency, very little of the product is used. At these small usage levels, Aclame, like other high potency sweeteners, has essentially no impact on the caloric content of foods. When used to sweeten in place of sugar it can help to substantially reduce calories.

HIGHLY STABLE, EVEN WHEN THE HEAT IS ON.

Aclame's unique structure assures excellent stability, effectively minimising potential problems with processing as well as extending shelf-life. Aclame's stability profile enables it to perform exceptionally well, even in foods that require high-temperature conditions such as baking.

Also, by offering superior stability across a broad range of pH levels and processing conditions, Aclame can be used in many different applications.

CONSIDER THE LIQUID ASSETS.

Aclame's excellent solubility in water and other polar solvents makes it an attractive sweetener to use in liquid products such as soft drinks and syrups, especially when the sweetener needs to be added in dry form.

Since Aclame has excellent hydrolytic stability, the quality and level of sweetness in a liquid system are maintained over time.

A LITTLE GOES A LONG WAY.

One of the most important properties in a sweetener is its potency.

Aclame is 2,000 to 3,000 times sweeter than sugar itself. Because this level of potency is so high, you'll use less Aclame to achieve the sweetness you desire. Utilising only a small amount of the product can simplify handling and processing techniques, making Aclame very easy to use.

A VERSATILE PERFORMER.

Aclame delivers superior sweetener performance in everything from confections and baked goods, to ice creams and beverages.

Since the sweetness profile of Aclame is so similar to sugar, Aclame is often used as the sole source of sweetness. However, in those instances when a unique sweetness is desired for a product, Aclame is completely compatible with other high intensity sweeteners.

With so much versatility to offer, Aclame will make it easier for you to develop the kinds of innovative foods today's sophisticated consumers are demanding.

ADD THE EXPERIENCE AND EXPERTISE OF PFIZER FOR COMPLETE SATISFACTION.

Pfizer has a thorough knowledge of food technologies.

We also have considerable product development expertise and resources, with a food technology laboratory in Sydney and access to resources in the United States.

Pfizer also has an excellent portfolio of other high-performance ingredients. These include:

- Litesse®, a one-calorie-per-gram bulking agent which helps maintain the bulking attributes of sugar in sugar-free foods.
- Dairy-Lo®, an all natural milk protein which provides creamy texture and mouthfeel in reduced fat foods.
- Veltol®, a flavour enhancer that helps round out and balance flavour profiles.

OUR KNOWLEDGE AND RESOURCES ARE AT YOUR DISPOSAL.

If desired, we can use our extensive knowledge and resources to help you develop new low-joule foods.

When you put it all together, there's only one conclusion: Life just got sweeter.

Potency.

A little goes a *long* way.

Aclame has a level of sweetness that is approximately 2,000 to 3,000 times greater than sucrose at typical usage levels. It depends upon the application and the desired sucrose equivalency.

Compared to other sweeteners in the marketplace, Aclame has a level of sweetness potency that is significantly greater.

Maximum Sweetness Potency in Water	Potency Frequently Reported	Sucrose Potency at		
		2%	**8%**	**10%**
Sucrose	1.0	1.0	1.0	1.0
Acesulfame K	200	204	77	34
Aclame	**2000**	**4500**	**2355**	**1640**
Aspartame	200	250	143	107
Na Cyclamate	30	26	27	18
Na Saccharin	300	510	188	0
Sucralose	600	614	520	385

Aclame's sweetness potency greatly exceeds that of other sweeteners.

Suggested Usage Levels of Aclame.

A single kilogram of Aclame provides the sweetening potency of between 2 metric tons and 3 metric tons of sugar. Typically, usage levels for Aclame range from 20 to 200ppm.

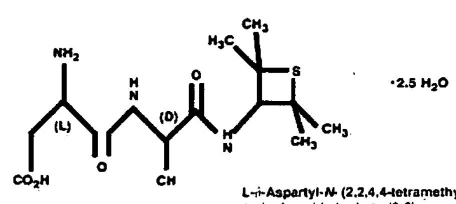
Alitame is a crystalline, non-hygroscopic dipeptide-based sweetener with a unique structure that enables high levels of sweetness and stability.

Aclame Suggested Usage Levels Application	Use Level (ppm)	Sucrose Matched	Application	Use Level (ppm)	Sucrose Matched
Soft drinks:			Flavoured yoghurt	20 30	8 10%
Lemonade	40 45	10%	Custard	10 15	5.0%
Raspberry	45 50	11%	**Baked Goods:**		
Orange	45 50	12%	Muffin	80 100	15.3%
Cordial:			Cake	130 150	29.5%
Fruit	30 - 35	9%	**Other:**		
No fruit	35 40	9%	Tabletop tablets	1 2	1 tspn 4.4g
Dairy:			Tinned fruit (pineapple)	60 90	45 Brix
Ice Cream	50 70	18%	Jelly	55 65	15%
Flavoured milks	10 15	4%	Caramel bites	100 220	52%
Fruit Yoghurt (made up)	20 30	7.5%	Chocolate topping	60 70	42%

Due to its high sweetness levels, Aclame can be used in small quantities to achieve desired sweetness.

It is a member of the L-∂-Aspartyl-D-alanine amide series discovered by Pfizer Food Science in which the alanine carboxyl group is terminated as an amide of a novel amine (2,2,4,4-tetramethylthietanyl amine).

Alitame Structure.



L-α-Aspartyl-N-(2,2,4,4-tetramethyl-3-thietanyl)-D-alaninamide hydrate (2:5)
$C_{14}H_{25}N_3O_4S$-2.5 H2O
mw 376.5
CAS Registry Number: 99016-42-9

Alitame is a crystalline, non-hygroscopic powder–its unique structure enables high levels of sweetness and stability.

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Solubility.

Consider the *liquid* assets.

Due to Aclame's excellent solubility in most polar solvents, the sweetness of the product can be added as a solution or neat material.

ACLAME SOLUBILITY.

Solvent	Solubility (%W/V), 25°C
Water	13.1 (isoelectric pH 5.6)
Methanol	41.9
Ethanol	61.0
Propylene glycol	>40
Chloroform	0.02
n-Heptane	0.001

Due to its outstanding solubility, Aclame is easy to process in solution and can be used in an extensive range of foods.

Aclame can be added to the food system from a stock solution or as the dry material dissolved in available liquids from the formulation.

At Aclame's isoelectric point of pH 5.6, it is 13.1% soluble in water (w/v) at 25°C. Aclame is equally soluble in most liquid systems encountered in food applications.

The exceptional stablility of Aclame in solution, even at high temperatures, facilitates usage and processing of the product—making Aclame a very versatile sweetener for many different kinds of foods such as low calorie beverages and syrups.

Pfizer FOOD SCIENCE

ACLAME™
Life Just Got Sweeter

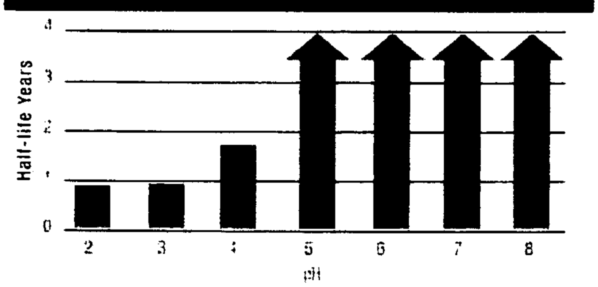
Stability.

Highly stable, *even* when the HEAT is on.

The unique structure of Aclame allows the product to deliver maximum stability across a wide range of pH levels and under many different food processing conditions.

This effectively reduces the potential for processing conflicts, while also increasing ease of use and extension of shelf life.

Stability of Aclame in Buffer Solutions at 23°C



Aclame offers excellent stability over a wide pH range, including lower pH aqueous systems.

Aclame is also very stable in aqueous environments. This provides the opportunity to use Aclame in a greater variety of foods including pasteurized processed and high temperature processed neutral pH food systems as well as confectionery and baked goods.

Additionally, Aclame offers excellent stability in lower pH aqueous systems.

At elevated temperatures, Aclame solutions of varying pH levels show good hydrolytic stability. Thus, Aclame provides thermal stability when thermal processing is warranted.

Elevated Temperature Stability of Aclame

100° C	13.5*	13.4	12.6
115° C	2.1*	2.1	2.1

*Half life in hours

Concentrated Aclame solutions provide excellent stability when held at elevated temperatures.

These high levels of stability give food technologists extensive versatility in developing foods that will meet the diversified needs of today's consumers.

ACLAME™
Life Just Got Sweeter

Pfizer FOOD SCIENCE

Taste.

Adding *sweetness*, <u>not</u> calories.

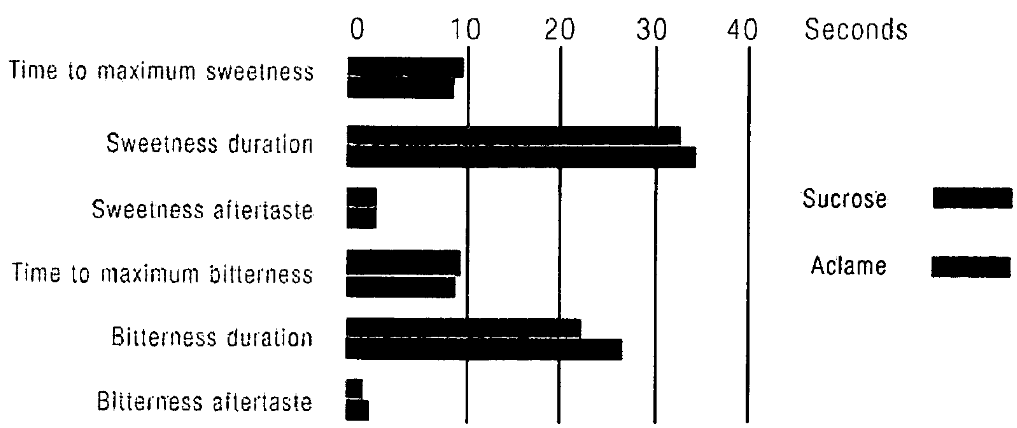
Sensory analysis indicates that Aclame's sweetness profile is similar to that of sugar. As a result of its unique composition, the product delivers a clean sweetness closely resembling the actual sweetness of sugar. When tested in water versus a 10% sucrose equivalent, Aclame performed exceedingly well, providing a very high level of sweetness potency.

The product's outstanding performance characteristics give it excellent versatility, allowing Aclame to be used alone or blended with other sweeteners to create the flavour profile and sweetness adaptations that are right for you.

Aclame has a caloric content of just 1.4 kcal (5.85 joules) per gram. And because of the product's exceptional potency, only small amounts are necessary to achieve desired sweetness.

Thus, while Aclame itself has essentially no impact on the caloric content of foods, when used as a replacement for sugar it can significantly reduce calories.

SWEETNESS AND BITTERNESS IN WATER AT 10% SUCROSE EQUIVALENCY.



Aclame has a sweetness and flavour profile similar to sugar.

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ACLAME MAXIMUM STABILITY.

Maximum Stability in Various Applications			
Product	Process	Conditions	Aclame
Water, unbuffered	HTST	pH 3-5.4	>97%
Water, buffered	Batch Pasteurization	pH 3-7	>98%
Tablets	Lactose Carrier	23°C and 37°C x 2 years	Avg. 91%
Granulated Blends	Maltodextrin Carrier	23°C and 37°C x 2 years	Avg. 88%
3% Solution	Water Carrier	23°C and 30°C x 2 years	>91%
Yellow Cake	Conventional Baking	350°F x 35 min	>75%
Cookies	Conventional Baking	375°F x 9 min	>75%
Frozen Yogurt	HTST	180°F x 30 sec	95%
Sugar Free Hard Candy	Batch Depositing	Addition with flavour and acid	85%
Lemon-Lime Soda	Conventional Process	23°C x 1 year and 30°C x 25 weeks pH 2.8	>70%

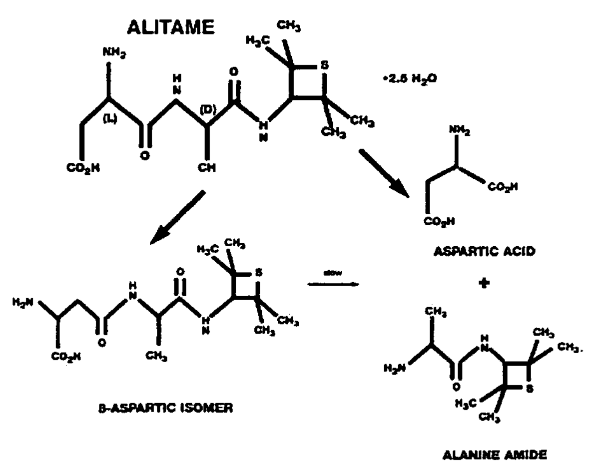
High levels of stability ensure that Aclame is adaptable to a wide variety of food processing applications.

Although Aclame has good stability some hydrolysis and isomerization can occur.

The major pathway involves hydrolysis of the aspartylalanine dipeptide bond to give aspartic acid and alanyl- 2,2,4,4-tetramethylthietane amide ("alanine amide"). The aspartic rearrangement common to all peptides bearing terminal aspartic acid, also occurs to give the aspartic isomer of Aclame.

This rearranged dipeptide hydrolyzes at a slower rate than Aclame to give the same product as those arising from the parent compound. No cyclization to diketopiperazine or hydrolysis of the alanine amide bond is detectable in solutions of Aclame that have undergone up to 90% hydrolysis. All three major products of hydrolysis and isomerization are completely tasteless at levels that are possible in foods.

ACLAME HYDROLYSIS AND ISOMERIZATION.



A minimal amount of hydrolysis and isomerization may occur in Aclame when used in some applications. However, this has no impact on taste.

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ACLAME™
Life Just Got Sweeter

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